Kenyon&Kenyon

Steven Lee
Direct 212.908.6305
slee@kenyon.com

Kenyon & Kenyon LLP
One Broadway
New York, NY 10004-1007
212.425.7200
Fax 212.425.5288

April 30, 2013

Via ECF

Honorable Madeline Cox Arleo, U.S.M.J.
United States District Court for the District of New Jersey
Martin Luther King, Jr. Federal Building & U.S. Courthouse
50 Walnut Street, Rm. MLK 2A
Newark, NJ 07101

Re: *Novartis Pharmaceuticals Corporation, et al., v. Wockhardt USA LLC, et al.*, Civil Action No. 12-cv-03967-SDW-MCA
Novartis Pharmaceuticals Corporation et al. v. Actavis LLC et al., Civil Action No. 13-cv-1028-SDW-MCA
Novartis Pharmaceuticals Corporation et al. v. Accord Healthcare Inc. et al., Civil Action No. 13-2379-SDW-MCA

Dear Judge Arleo:

On behalf of Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. (collectively, "Sun"), defendants in C.A. No. 12-cv-03967, we write opposing Novartis's motion to consolidate.

Novartis has not met its burden of establishing that consolidation of Civil Action Nos. 13-1028 and 13-2379 (collectively, the "2013 actions") with Civil Action No. 12-3967 (the "2012 action") will avoid unnecessary cost or delay. While the 2012 and 2013 actions share some common issues of fact, they are different in these critical ways: the 2012 action concerns a different product (Zometa Ready-to-Use, "RTU"); the defendants in the 2012 action have not launched their RTU products; in fact, the FDA cannot approve their RTU products until December 2014 or an earlier decision by this court that Novartis's '241 patent is invalid or not infringed; until then, Novartis continues to enjoy a monopoly on RTU; and patients continue to pay monopoly, not generic prices for their RTU. And because defendants in the 2012 action have not launched their RTU products, and cannot launch their RTU products, there are no damages available in the 2012 case, and Novartis is not entitled to a trial by jury. Finally, the 2012 action is far advanced of the 2013 actions with which Novartis seeks consolidation.

Consolidation will inevitably slow down the 2012 action, preventing its resolution before December 2014, and thus delaying competition with Novartis for the RTU market. In the 2012 action, the parties have answered, a scheduling conference has been held, and a scheduling order entered. The parties have exchanged contentions, and completed claim construction. Discovery is

ongoing (the parties have exchanged over a million pages of documents), and dispositive motions may be filed as of February 2014. In contrast, in one of the 2013 actions, some of the parties have answered, some have not; in the other, it is not clear that any parties have answered. In the 2013 actions, no initial scheduling conference has been held; no contentions exchanged; no claim construction begun, let alone completed. Plainly, consolidation of the 2012 action with the 2013 actions will delay resolution of the consolidated actions, and generic competition for the RTU products. Consolidation will not only have procedural effects but also substantive effects. Sun, therefore, opposes consolidation.

If the Court nonetheless decides that consolidation, on balance, would facilitate the administration of justice, then defendants request that the Court consolidate for pre-trial purposes only, and maintain the 2012 action on its present schedule.

Argument

Novartis has the burden to show that any interests of judicial economy outweigh the delays, expense, confusion, and prejudice that would result from consolidation. *See Landsman & Funk, P.C. v. Skinder-Straus Associates*, No. 08-3610 (KSH), 2012 WL 2476371, at * 2 (D.N.J. June 27, 2012). Because C.A. No. 13-1028 presents unique issues involving damages, because Novartis is not entitled to a jury trial for the 2012 action, because the 2012 action has proceeded much further than the 2013 actions, and because consolidation will prejudice Sun and the public, Novartis cannot meet its burden, and the Court should thus deny Novartis's motion to consolidate.

Novartis cites three cases for the proposition that "courts routinely consolidate ANDA matters for the convenience of the courts and the parties." Novartis Br. at 7. But the consolidation Novartis seeks is not routine. The cases upon which Novartis relies are inapposite, for none consolidated ANDA actions where one action—but not the other—involved (i) a jury demand or (ii) a request for monetary damages; where some products had been launched, while others could not be, and in fact the FDA was enjoined from approving them. Indeed these cases are distinguishable from those cases in at least three key respects. First, unlike in those cases, Novartis has requested a jury trial in C.A. No. 13-1028 but is not entitled to one in the 2012 action. Second, monetary damages were not requested in those actions, whereas Novartis has requested monetary damages in C.A. No. 13-1028, but not in the 2012 action. Finally, in Novartis's cases, the defendants were similarly situated, marketing the same products, and would not have been prejudiced from a delay due to consolidation—whereas, here, Sun and Wockhardt, the defendants in the 2012 action, the only parties seeking to market an RTU product, would be prejudiced if the Court does not determine whether the '241 patent is invalid and not infringed before Sun's 30-month stays expire.

1. The Court Should Not Consolidate the Actions Because C.A. No. 13-1028 Presents Additional Complicated Issues Involving Damages.

Where, as here, only some facts and legal issues overlap, courts have denied motions to consolidate. *See Microbilt Corp. v. Fidelity Nat'l Info. Servs.*, No. 12-3861 (JAP), 2012 WL 4955267 (D.N.J. Oct. 16, 2012) (denying motion to consolidate and explaining that "mere presence of common issues" is not enough for consolidation); *Leviton Mfg. Co. v. Nicor, Inc.*, No. 04-0424, 2007 U.S. Dist. LEXIS 8920 (D.N.M. Jan. 8, 2007) (denying motion to consolidate because, among other reasons, while the two patents in the two actions share the same specification, they do not share the same claims).

Because some generic drug manufacturers have launched low-cost alternatives to Novartis's Zometa products, Novartis has requested monetary damages in C.A. No. 13-1028. The request for monetary damages introduces a complex set of issues that are not present in the 2012 action. See, e.g. In assessing damages, the parties will have to confront separate issues relating to advice of counsel, royalties, lost profits, and price erosion. For instance, in determining what would have constituted a "reasonable royalty" at time of a hypothetical negotiation, the parties will have to consider fifteen "Georgia-Pacific" factors, including "the nature and scope of a license that would have been granted to a hypothetical licensee and the business risks faced by the hypothetical licensee." *Novopharm Ltd. v. Torpharm, Inc.*, 181 F.R.D. 308 (E.D.N.C. 1998). A "lost profits" theory of damages would bring with it similar complexities, requiring an analysis of (i) market demand for Zometa products; (ii) Novartis's ability to meet demand; (iii) the absence of non-infringing substitutes; and (iv) the amount of profit that Novartis would have made on allegedly lost sales "but for" defendants' supposed infringement. *See id.* at 311.

The types of sales, marketing, and accounting evidence that would be required to address these issues would also increases the length of discovery and trial of any consolidated action. *See F & G Scrolling Mouse L.L.C. v. IBM Corp.*, 190 F.R.D. 385, 399 (M.D.N.C. 1999) ("The damage phase has been found to be complex when damages are predicated on lost profits and/or reasonable royalties which can involve expert witnesses and voluminous financial data.")

2. The Court Should Not Consolidate the Actions Because While Novartis Has Requested a Jury Trial for C.A. No. 13-1028, It Is Not Entitled to a Jury Trial for the 2012 Action.

The Court should not consolidate the actions because while Novartis has requested a jury trial for C.A. No. 13-1028, it is not entitled to one for the 2012 action; and "courts have often declined to consolidate cases requiring two different factfinders." *See Servants of Paraclete v. Great Am. Ins. Co.*, 866 F. Supp. 1560 (D.N.M. 1994) (denying motion to consolidate); *see also Peter Condakes Co., Inc., v. Sandler Bros.*, No. 09-CV-168-P-S, 2009 WL 2382785, at *1 (D. Me. July 29, 2009) (denying motion to consolidate because, among other reasons, "the two cases will require two different factfinders"--a jury having been demanded in one case but not in the other); *U.S. EPA v. City of Green Forest, Arkansas*, 921 F.3d 1394 (8th Cir. 1990) (denying

motion to consolidate because despite the assertion that the actions presented the same issues, one action involved damages to be tried before a jury while the other action was to be tried before a court).

Novartis has not requested a jury trial in the 2012 action because Novartis is entitled only to equitable relief, for no defendant has marketed a product subject to that action. *See In re Apotex*, No. 690, 49 Fed. Appx. 902, 903 (Fed. Cir. Oct. 9, 2002) (explaining that when a case involves only "possible infringement, and which there can be no damages because no infringing products have been marketed, the only relief that is before the district court is equitable in nature.") Consolidation under a single schedule with a single trial thus makes little sense, because different factfinders would be required for the equitable issues of the 2012 action versus the issues involving damages of the 2013 action.

3. The Court Should Not Consolidate the Actions Under a Single Schedule Because the 2012 Action, Having Advanced Further in the Discovery Process, Would Be Delayed.

Because the 2012 action has advanced well into discovery, the Court should not consolidate it with the recently-filed 2013 actions under a single schedule. Courts will deny a motion to consolidate "if consolidation will cause delay in the processing of one or more of the individual cases" or "when one of the actions has proceeded further in discovery than the other." *See* 9 Charles Alan Wright & Arther R. Miller, Federal Practice & Procedure 2383 (3d ed. 2006); *see also Aerotel, Ltd. v. Verizon Commc'ns Inc.*, 234 F.R.D. 64, 67 (S.D.N.Y. 2005) (denying motion to consolidate because, among other reasons, in one action the parties had completed significant discovery, whereas in the other action the parties had conducted only minimal discovery).

The 2013 actions lag far behind the 2012 action, in several ways. First, Novartis filed its complaint in C.A. No. 13-2379 just earlier this month, and thus those defendants may not answer, move, or otherwise respond for months. Second, the docket of C.A. No. 13-2379 does not reflect that Novartis has even properly served Hikma Farmaceutica S.A., a foreign defendant, and thus this defendant may have even longer to respond to Novartis's complaint. Third, the defendants in C.A. No. 13-1028 only recently answered, moved, or other otherwise responded, on April 25, to Novartis's amended complaint. Fourth, in neither 2013 action have the parties had an initial scheduling conference under Fed. R. Civ. P. 26(f)—and contentions under the local patent rules are not due until afterwards.

The 2012 action, in contrast, has advanced well into discovery. The parties have filed contentions under the local patent rules, produced over a million pages of documents, and finished claim construction and all other proceedings under the local patent rules. And defendants have noticed Novartis employees for deposition. The parties are on track to finish fact discovery by October 2, 2013 and file dispositive motions by March 27, 2014, as set in the scheduling order. *See* C.A. No. 123967, Dkt. No. 43. But if the Court consolidates the actions under one schedule, then the 2012 action would have to wait for the other actions to catch up.

See PB&J Software, LLC v. Acronis, Inc., No. 4:12-CV-690 SNLJ, 2012 U.S. Dist. LEXIS 145994, at *6 (E.D. Mo. Sept. 25, 2012) (denying motion to consolidate because, among other reasons, one action had already entered discovery and "would have to wait for the defendants to 'catch up' to it in the consolidated action").

4. The Court Should Not Consolidate the Actions Because Consolidation Will Prejudice Sun and the Public.

The Court should not consolidate the 2012 action with the 2013 actions because consolidation will prejudice Sun and the public. Indeed, the added issues, the added discovery, and the slower schedule from consolidation will delay Sun from marketing its low-cost RTU and Reclast products. Sun's ANDAs for RTU and Reclast are subject to 30-month stays, expiring December 2014 and January 2015, respectively. Consolidation will prevent the Court from determining, before the stays expire, whether the '241 patent is invalid and not infringed. Congress enacted the Hatch-Waxman Act, though, to expedite resolution of ANDA cases and put generic forms of drugs on the market as soon as the branded company's patent exclusivity ends. *See Caraco Pharms. Labs., Ltd. v. Novo Nordisk*, 132 S.Ct. 1670, 1676 (2012); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007). Consolidation would thus contravene the intent of the Hatch-Waxman Act, by delaying Sun from marketing its low-cost generic products. The prejudice to Sun is magnified because other defendants have launched generic products. And in that market, Sun cannot compete with its RTU Zometa and Reclast products.

The prejudice to the public is also magnified because Sun has 180 days of exclusivity on RTU Zometa: the FDA is barred from granting final approval to any other defendant's ANDA for ready-to-use Zometa until Sun's exclusivity expires. The 180 days of exclusivity will begin either from the date Sun begins commercial marketing of its generic drug product, or from the date of a court decision finding the patent invalid or not infringed, whichever is first. Consolidation would thus not only delay Sun from marketing its ready-to-use Zometa, it would delay all low-cost RTU products from entering the market.

The Court should, then, deny Novartis's motion to consolidate, because consolidation would delay this action, delaying the launch of generic RTU, to the prejudice of the 2012 case defendants and the public.

5. Should the Court Consolidate the Actions, It Should Maintain the 2012 Action on a Separate Track, to Avoid Prejudicing Sun and to Quickly Resolve the Action Consistent with the Hatch-Waxman Act.

If the Court decides that consolidation would, on balance, avoid unnecessary cost or delay, then Sun requests that the Court maintain the 2012 action on a separate schedule and hold a separate trial for the 2012 action because a quick resolution of the 2012 action would be consistent with the goal of the Hatch-Waxman Act to speed the introduction of a generic drug product (RTU Zometa) to the benefit of the public. And to ameliorate any worries over

duplicative proceedings from maintaining the 2012 action on a separate track, at least one of the few defendants that has been sued on the '241 patent but is not part of the 2012 action has consented to being put on the current, faster track of the 2012 action.

Conclusion

Consolidation would substantially delay marketing of generic RTU to the detriment of the 2012 action defendants and the public. That delay is of Novartis's own making. When Novartis agreed to the schedule of the 2012 action, it had already obtained U.S. Patent 8,324,189, the patent that supposedly triggered the 2013 actions. As Judge Wigenton noted, Novartis delayed bringing the first of the 2013 actions, potentially for gamesmanship. *See* March 1, 2013 Tr. at 76:11-12. That Novartis brought those actions late should be no reason to penalize the defendants in the 2012 action with a slower schedule. For this reason and the other reasons identified in this brief, Sun requests that the Court deny Novartis's motion to consolidate. Should the Court, however, be disposed to grant Novartis's motion, Sun and Wockhardt request that the Court separate the 2012 action for trial, and maintain the 2012 action on its current schedule.

Very truly yours,

Steven Lee

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